UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,064	10/05/2005	Oliver Schadt	MERCK-3067	6539

23599 7590 02/24/2010

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
02/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,064	SCHADT ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-13,15,16,23 and 28-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4,6-10,13,15,23 and 28-36* is/are allowed.

6)☒ Claim(s) *11,12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *26 January 2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 January 2010 has been entered.

2. The rejections under 35 U.S.C. 1`12 1st and 2nd paragraph have been overcome by the amendment filed 26 January 2010.

3. The 35 U.S.C. 103(a) rejection has been overcome by the amendment filed 26 January 2010.

4. In the current claim set, claims 1-4, 6-13, 15-16, 23, and 28-36 are pending and are being examined on the merits.

Priority

5. The priority date for the instant application is 10 March 2004.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11, 12, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of obesity (5-HT_{2C}), anxiety (5-HT_{2C}), depression (5-HT_{2A} and 5-HT_{2C}), obsessive-compulsive disorders (5-HT_{2A} and 5-HT_{2C}), male sexual dysfunction (5-HT_{2C}), epilepsy (5-HT_{2C}), urinary incontinence (5-HT_{2C}), hot flushes (5-HT_{2C}), bulimia nervosa (5-HT_{2C}), substance abuse (5-HT_{2C}), schizophrenia (5-HT_{2A} and 5-HT_{2C}), glaucoma (5-HT_{2C}), dementia-associated disorders (5-HT_{2A}), pain (5-HT_{2A}), memory improvement and promotion of learning (both 5-HT_{2C}),

addiction (5-HT_3), pruritis (5-HT_3), emesis (5-HT_3), fibromyalgia (5-HT_3), migraine (5-HT_3), rheumatic diseases (5-HT_3), anxiety (5-HT_3), psychosis (5-HT_3), nociception (5-HT_3), cognitive function (5-HT_3), and amyotrophic lateral sclerosis (5-HT_6), does not reasonably provide enablement for Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treating a disease influenced by a 5-HT receptor with a compound consisting of a pyrazole modified with a phenyl of pyridine at its 1-position. Thus, the claims taken together with the specification imply compounds of claim 1 can treat disorders influenced by 5-HT receptors.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Bishop et al. (*Expert Opinion on Therapeutic Patents*, **2003**, *13(11)*, 1691-1705) teach that additional studies are required to determine if 5-HT_{2C} receptors are valid targets for the treatment of Alzheimer's disease (page 1693, section 2.5). 5-HT_{2C} is associated with the following disorders: obesity (section 2.1, page 1692); anxiety, depressions, and obsessive-compulsive disorders (page 1692, section 2.2); male sexual dysfunction (page

1693, section 2.3); epilepsy (page 1693, section 2.4); urinary incontinence (page 1693, section 2.6); hot flushes (page 1694, section 2.7); and bulimia nervosa, substance abuse, schizophrenia, and glaucoma (page 1694, section 2.8).

Roth et al. (*Expert Opinion on Therapeutic Patents*, **2001**, *5(6)*, 685-695) teach that 5-HT_{2A} receptors are associated with schizophrenia, depression, obsessive-compulsive disorder, pain, and dementia-associated mental disorders (tables 1 and 2, page 686).

Thompson et al. (*Expert Opinion on Therapeutic Patents*, **2007**, *11(4)*, 527-40) teach that 5-HT_{2C} receptors are associated with memory impairment and promotion of learning (page 534, section 4.4). 5-HT_3 receptors are associated with addiction, pruritis, emesis, fibromyalgia, migraine, rheumatic diseases, anxiety, psychosis, nociception, and cognitive function. In addition chronic heart pain and bulimia may be associated with 5-HT_3 (page 531, column 1, paragraph 2).

Slassi et al. (*Expert Opinion on Therapeutic Patents*, **2002**, *12(4)*, 513-27) teach that 5-HT_6 is associated with amyotrophic lateral sclerosis (page 517, column 2, paragraph 2).

(5) The relative skill of those in the art:

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position (MD's, PhD's, or those with advanced degrees and the requisite experience in diseases influenced by 5-HT receptors).

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for treatment of obesity (5-HT_{2C}), anxiety (5-HT_{2C}), depression (5-HT_{2A} and 5-HT_{2C}), obsessive-compulsive disorders (5-HT_{2A} and 5-

HT_{2C}), male sexual dysfunction (5-HT_{2C}), epilepsy (5-HT_{2C}), urinary incontinence (5-HT_{2C}), hot flushes (5-HT_{2C}), bulimia nervosa (5-HT_{2C}), substance abuse (5-HT_{2C}), schizophrenia (5-HT_{2A} and 5-HT_{2C}), glaucoma (5-HT_{2C}), dementia-associated disorders (5-HT_{2A}), pain (5-HT_{2A}), memory improvement and promotion of learning (both 5-HT_{2C}), addiction (5-HT_3), pruritis (5-HT_3), emesis (5-HT_3), fibromyalgia (5-HT_3), migraine (5-HT_3), rheumatic diseases (5-HT_3), anxiety (5-HT_3), psychosis (5-HT_3), nocicepion (5-HT_3), cognitive function (5-HT_3), and amyotrophic lateral sclerosis (5-HT_6).

However, the specification does not provide guidance for treatment of Alzheimer's disease (5-HT_{2C}).

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 11, 12, and 16 and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Conclusion

8. Claims 1-4, 6-10, 13, 15, 23, and 28-36 appear free of the prior art of record.

9. The claims recited in the preceding paragraph appear free of the prior art of record because Schadt et al. (PGPub 20060276650 of application 10/551905, filed 5 October 2005, reference A9 of 31 March 2009 IDS) teach compounds that are embraced by claim 1 of 10/552064, but cannot be considered prior art because applicants filed a terminal disclaimer (which was approved 7 August 2007) against this application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624